



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2006-D-0157]

Guidance for Industry: Biologics License Applications for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic and Immunologic Reconstitution in Patients With Disorders Affecting the Hematopoietic System; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Guidance for Industry: Biologics License Applications for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic and Immunologic Reconstitution in Patients With Disorders Affecting the Hematopoietic System" dated March 2014. The guidance document provides recommendations for manufacturers, generally cord blood banks, to apply for licensure of minimally manipulated, unrelated allogeneic placental/umbilical cord blood, for hematopoietic and immunologic reconstitution in patients with disorders affecting the hematopoietic system that are inherited, acquired, or result from myeloablative treatment. The guidance document is intended to assist manufacturers in obtaining a biologics license. The guidance contains information about the manufacture of minimally manipulated, unrelated allogeneic placental/umbilical cord blood and how to comply with applicable regulatory requirements. The guidance announced in this document finalizes the draft guidance of the same title dated June 2013 and supersedes the guidance entitled "Guidance for Industry: Minimally Manipulated, Unrelated, Allogeneic

Placental/Umbilical Cord Blood Intended for Hematopoietic Reconstitution for Specified Indications" dated October 2009.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Tami Belouin, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled "Guidance for Industry: Biologics License Applications for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic and Immunologic Reconstitution in Patients with Disorders Affecting the Hematopoietic System" dated March 2014. The guidance document provides recommendations for manufacturers to apply for licensure of minimally

manipulated, unrelated allogeneic placental/umbilical cord blood, for hematopoietic and immunologic reconstitution in patients with disorders affecting the hematopoietic system that are inherited, acquired, or result from myeloablative treatment. The guidance document is intended to assist manufacturers obtain a biologics license. The guidance contains information about the manufacture of minimally manipulated, unrelated, allogeneic placental/umbilical cord blood and how to comply with applicable regulatory requirements.

In the Federal Register of June 17, 2013 (78 FR 36196), FDA announced the availability of the draft guidance of the same title dated June 2013. FDA received a few comments on the draft guidance and those comments were considered as the guidance was finalized. Minor changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance of the same title dated June 2013 and supersedes the guidance entitled "Guidance for Industry: Minimally Manipulated, Unrelated, Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic Reconstitution for Specified Indications" dated October 2009.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

Elsewhere in this issue of the Federal Register, we also are announcing the availability of another, related guidance entitled "Guidance for Industry and FDA Staff: Investigational New Drug Applications for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic and Immunologic Reconstitution in Patients with Disorders Affecting the Hematopoietic System." That guidance supersedes the document entitled

“Guidance for Industry and FDA Staff: Investigational New Drug Applications (INDs) for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic Reconstitution for Specified Indications” dated June 2011.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 201 have been approved under OMB control number 0910-0572; 21 CFR part 211 have been approved under OMB control number 0910-0139; 21 CFR part 600 have been approved under OMB control number 0910-0308; 21 CFR parts 601 and 610, and Form FDA 356h have been approved under OMB control number 0910-0338; and 21 CFR part 1271 have been approved under OMB control number 0910-0543.

III. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: February 27, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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